

PATENT

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Rimma Mitelman 06/21/05
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Signature

RIMMA MITELMAN
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Attorney Docket No.: C7592(V)
Appellants: Chapple et al.
Serial No.: 10/025,237
Filed: December 19, 2001
For: Stabilization of Antibodies or Fragments Thereof

Group: 1751
Examiner: P. Kumar
Englewood Cliffs, New Jersey 07632
June 21, 2005

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BRIEF FOR APPELLANTS

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Sir:

Enclosed herewith are three (3) copies of an Appeal Brief for Appellants.

Please charge the \$500.00 fee to our Deposit Account No. 12-1155. Any deficiency or overpayment should be charged or credited to this Deposit Account. This authorization is submitted in triplicate.

Respectfully submitted,

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I. REAL PARTY IN INTEREST

The real party in interest is Conopco, Inc., d/b/a UNILEVER, a corporation of New York, having a place of business at 700 Sylvan Avenue, Englewood Cliffs, New Jersey 07632.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Fifteen (15) claims are presently pending.

B. STATUS OF ALL THE CLAIMS

1. Claims rejected – Claims 1-2, 4-16.

C. CLAIMS ON APPEAL

Claims 1-2, 4-16 are on appeal.

IV. STATUS OF AMENDMENTS

No amendments were presented after Final Rejection.

V. SUMMARY OF THE INVENTION

The application relates to antibody granules and methods preparing thereof. See page 2, line 34 – page 3, line 7 of the specification. It has now surprisingly been found that it is possible to incorporate antibodies into detergent compositions in a stable manner if the antibodies are granulated with simple salts, such as sodium or potassium salts. This is the converse to granulation of enzymes, whereby complicated measures have to be taken in the granulation technology in order to provide the required stability and the lifetime of the enzyme. Moreover, it was surprisingly found the antibody activity was improved when they were stored in the granulated form, as compared to common protein storage methods. This therefore imparts a substantially improved lifetime of the antibody and its associated performance in a powdered form or product form. See page 2, lines 18-31 of the specification.

VI. ISSUES FOR APPEAL

The Issue that remains in the case is defined by the Examiner's rejections and is as follows:

Whether claims 1-2, 4-16 are rendered obvious, under 35 U.S.C. §103(a), by Hauwermeiren (WO 98/06811):

VII. GROUPING OF CLAIMS

All claims stand or fall together.

VIII. APPELLANTS' ARGUMENTS

Whether claims 1-2, 4-16 are rendered obvious, under 35 U.S.C. §103(a), by Hauwermeiren (WO 98/06811).


The Examiner alleges that Hauwermeiren teaches a granule consisting essentially of an antibody (or fragment thereof) and more than 80% alkali metal salt.

The Examiner points to page 7, fourth paragraph of Hauwermeiren, but that paragraph merely teaches antibody granules in very general terms, without disclosing any amount of alkali metal salt, let alone the amount recited by the present claims. The Examiner then also points to example 7, Formulation 4. That example, however, merely lists "dry additives" under which a number of individual, separate additives are listed. The individual components can only be interpreted as separate ingredients, since the plural "additives" is used, meaning that the separate ingredients are present, not the single additive. Furthermore, the legend to examples on page 50 of lists "antibody" separately – although the dilution of 1:1000 is mentioned, it is not taught in what. Furthermore, studying the legend further, it can be seen that the enzymes in example 7, Formulation 4 (protease, lipase, amylase) are separate commercial formulations marketed under separate trade names and even from separate suppliers. Thus, the example does not teach an antibody granule which contains both antibody and alkali metal salt. It merely teaches a detergent composition which comprises, among many other ingredients, an antibody and an alkali metal salt as separate ingredients. Appellants do not dispute that such compositions are known. Appellants' invention, however, relates to an antibody granule wherein the antibody is granulated with an alkali metal salt in an amount of more than 80%. Hauwermeiren does not teach or suggest such granule.

IX. CONCLUSION

Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the Examiner's final rejection.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Rimma Mitelman", written over a horizontal line.

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APPENDIX OF CLAIMS (37 C.F.R. 1.192(c)(9))

The text of the claims involved in the appeal is:

1. Antibody granule consisting essentially of:
 - (a) one or more antibodies, or fragments derived thereof,
 - (b) granulated with an alkali metal salt,wherein the granule consists of more than 80% of the alkali metal salt.
2. Antibody granule according to claim 1, wherein the alkali metal is sodium or potassium.
3. (Cancelled)
4. Antibody granule according to claim 1, further comprising a polymer.
5. Antibody granule according to claim 1, wherein the antibody has a chemical equilibrium constant K_d for its antigen of less than $1 \cdot 10^{-4}$.
6. Antibody granule according to claim 1, wherein the chemical equilibrium constant K_d for the antigen is less than $1 \cdot 10^{-7}$.
7. A detergent composition comprising the antibody granule of claim 1.
8. An enzymatic stain bleaching composition comprising the antibody granule of claim 1.
9. An enzymatic anti dye-transfer composition comprising the antibody granule of claim 1.

10. Process for preparing an antibody granule according to claim 1, in which the antibody is granulated with an alkali metal salt.
11. Process according to claim 10, whereby the temperature is of 30°C or higher.
12. Process according to claim 10, whereby the pH is kept at a value from 6.0 to 10.0.
13. Antibody granule according to claim 1, wherein the granule consists for more than 90% of the alkali metal salt.
14. Antibody granule according to claim 1, wherein the antibody has a chemical equilibrium constant K_d for its antigen of less than $1 \cdot 10^{-6}$.
15. Process according to claim 10, whereby the temperature is from 30°C to 80°C.
16. Process according to claim 10, whereby the pH is kept at a value from 7.0 to 9.0.